Clinical failure after percutaneous transluminal angioplasty of the superficial femoral and popliteal arteries

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Objective: Anatomic patency after percutaneous transluminal angioplasty (PTA) of the superficial femoral and popliteal arteries does not guarantee clinical success. The aim of this report is to determine the causes of clinical failure after PTA.

Methods: The records of all patients who have undergone PTA of the femoropopliteal arterial segment by our vascular group were retrospectively reviewed. Only patients with complete records and at least one postprocedure clinical and anatomic assessment within the same 30-day time interval were included. Success was defined according to the Society for Vascular Surgery / International Society for Cardiovascular Surgery Ad Hoc Subcommittee on Reporting Standards for Endovascular Procedures. Anatomic cumulative patency and clinical success were calculated according to life table analysis on an intent-to-treat basis.

Results: We identified 85 patients who met inclusion criteria. We treated 112 lesions with an average stenosis of 80% ± 16% and lesion length of 2.3 ± 1.8 cm. Technical failure occurred in six (5.4%) of 112 lesions. Cumulative clinical success was 69% at 1 year, 54% at 2 years, 49% at 3 years, and 40% at 4 years. Anatomic patency was 74% at 1 year, 62% at 2 years, 57% at 3 years, and 52% at 4 years. There were 45 clinical failures; of these, twenty-seven (60%) occurred in conjunction with anatomic failure. Anatomic failure was due to restenosis in 12 patients (44%), occlusion in eight patients (30%), and restenosis with progression of disease in six patients (22%). Anatomic failure at the time of the procedure occurred in one patient (4%). Clinical failure occurred despite anatomic patency in the remaining 18 patients (40%). Etiology for clinical failure in this latter group included progression of disease within the treated vessel in 12 patients (67%), iliac disease in three patients (17%), tibial disease in two patients (11%), and bypass graft failure in one patient (5%). Fifty percent of all 45 clinical failures were successfully treated with supplemental percutaneous procedures.

Conclusion: A PTA is an acceptable therapeutic option for the treatment of focal occlusive disease of the femoropopliteal arterial segment. Most clinical failures were due to anatomic failure, but a significant number occurred despite patency at the PTA site. Although primary clinical success rates were inferior to surgical bypass graft, supplemental PTA was possible in 50% of patients. Repeat percutaneous treatment may extend the interval of clinical success and may obviate the need for surgical bypass graft. (J Vasc Surg 2000;31:880-8.)

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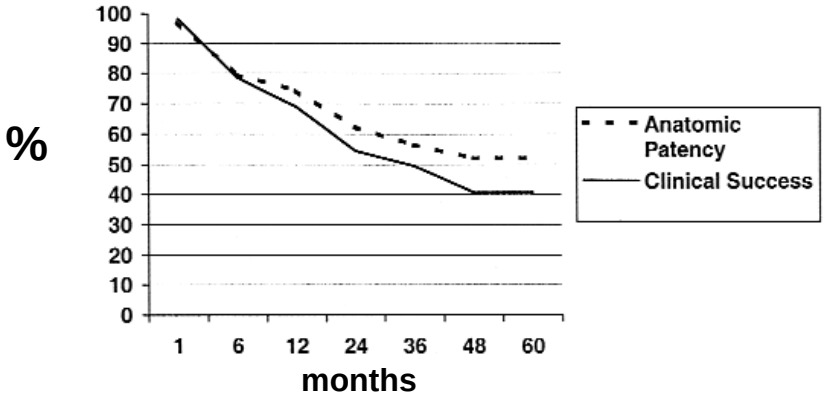
Percutaneous transluminal angioplasty (PTA) is one therapeutic modality for the treatment of focal occlusive disease of the superficial femoral artery (SFA) and the popliteal artery. Compared with surgical revascularization, it is less invasive, is less costly, and has a low incidence of complications.[1-8] Initial technical success rates of 90% to 95% have been achieved for stenotic lesions and of 80% to 95% for complete occlusions.[3,4,6,7]

Because of inconsistent reporting standards, the efficacy of femoropopliteal PTA remains controver-



Cumulative clinical success and anatomic patency rates after PTA of the femoropopliteal arterial segment.

Table I. Characteristics of femoropopliteal lesions that underwent PTA (n = 112)

Location of lesion	
SFA	84 (75%)
Popliteal artery	28 (25%)
Type of lesion	
Stenoses	104 (93%)
Occlusions	8 (7%)
Average degree of stenosis (%)	80 ± 16
Length of stenosis	
< 2 cm	81 (72%)
> 2–5 cm	22 (20%)
> 5–10 cm	9 (8%)
Runoff status	
Good (2-3 vessels)	69 (62%)
Poor (0-1 vessel)	43 (38%)

sial. Cumulative patency rates of 40% to 80% over 1 to 5 years have been reported.[3-8] The wide variability among the published results is due to differences in the criteria used to denote success and is due to differences in patient demographics and the types of lesions treated.

The primary goal of treatment is to achieve clinical success as measured by an improvement in walking distance, the resolution of rest pain, or limb salvage. Despite technical success and acceptable anatomic patency after PTA, improvement in clinical status is not always achieved.[3,9,10] The purpose of this report was to determine the clinical success and cumulative anatomic patency rates of femoropopliteal PTA performed by vascular surgeons at our institution and to determine the etiology of clinical failure. The outcome of clinical failure and the role of supplemental endovascular procedures to treat clinical failure were also evaluated.

METHODS

The records of all patients who underwent PTA of the femoropopliteal arterial segment by our vascular group since 1992 were reviewed. Repeat dilatations at sites previously treated with PTA were combined with primary PTA because the outcome is identical.[4,7,11-15] Only patients with complete records and at least one postprocedure clinical and anatomic assessment within the same 30-day interval were included. Patients who had undergone laser-assisted balloon angioplasty, atherectomy, and thrombolysis were excluded.

Risk factors, clinical symptoms, and the preprocedure resting ankle/brachial index (ABI) were noted in each patient. Diagnostic angiography was performed before intervention. The location and degree of each treated lesion and the runoff status were recorded. Simultaneous unilateral interventions were reported as separate lesions if they occurred in separate vascular beds (SFA vs popliteal artery).

Antegrade puncture was used to access the femoropopliteal lesion in most patients. Angioplasty procedures were performed using low-profile, high-pressure balloons equal to the diameter of the adjacent, normal arterial segment. All patients were given 5000 units of intravenous heparin before the PTA. Balloon inflation was performed for 30 to 60 seconds at pressures of 6 to 12 atm. Inflation was repeated twice and followed by angiographic assessment of the result. If a residual stenosis > 30% was present, angioplasty was repeated with a larger balloon. Selective stent placement was performed for a residual stenosis > 30% or a flow-limiting dissection. Primary stenting was not performed. Unless contraindicated, all patients were treated with aspirin. A full-dose of warfarin sodium (Coumadin) was administered if a stent was deployed.

Success, patency, and failure were defined according to the Society for Vascular Surgery/International

Table II. Life-table analysis of clinical success after PTA of the femoropopliteal arterial segment

Interval (mo)	*No. at risk at start of interval*	*No. of failures*	*No. withdrawn successfully*	*Interval failure rate (%)*	*Interval success rate (%)*	*Cumulative success (%)*	*SE (%)*
0-1	112	2	2	1.8	98.2	98.2	1.2
1-6	108	20	17	20.1	79.9	78.5	3.5
6-12	71	8	11	12.2	87.8	68.9	4.6
12-24	52	9	18	20.9	79.1	54.5	5.1
24-36	25	2	7	9.3	90.7	49.4	7.0
36-48	16	2	9	17.4	82.6	40.8	7.8
48-60	5	0	3	0	100.0	40.8	14.0
> 60	2	2	0	100.0	0	0	0

Society for Cardiovascular Society Ad Hoc Subcommittee on Reporting Standards for Endovascular Procedures.[16] *Technical failure* was defined as the inability to cross the lesion with a guidewire leading to termination of the procedure and was considered an immediate clinical and anatomic failure. *Immediate anatomic success* was defined as a residual stenosis < 30% at the completion of the procedure. A residual stenosis > 30% or flow-limiting dissection after PTA successfully treated with immediate stent deployment was not considered an immediate anatomic failure. All patients underwent at least one postprocedure clinical and anatomic assessment within the same 30-day interval. Our routine surveillance protocol includes a clinical evaluation, an ABI, and a color-flow duplex scan (CDS) at 24 hours, 1 month, 6 months, and 1 year after the procedure and then at yearly intervals. *Clinical success* was defined as improvement in walking distance that was greater than 50% in claudicants, resolution of ischemic rest pain, or limb salvage in patients with tissue loss. Assessment of walking distance and rest pain was determined by patient interview. *Intermediate and long-term anatomic patency* were defined as a restenosis < 50% at the site of PTA, which was assessed by angiography or CDS. In our vascular laboratory, a diameter reduction greater than 50% corresponds to a doubling of the peak systolic velocity across the stenotic segment as compared with the adjacent normal arterial segment.

Cumulative clinical success and anatomic patency were calculated for each lesion according to life table analysis on an intent-to-treat basis. Patients who failed clinically during the follow-up period were subjected to further review. The etiology of clinical failure was determined by anatomic information obtained with angiography and/or CDS. The management of clinical failures was also evaluated.

RESULTS

Since 1992, 98 patients underwent PTA of the SFA or popliteal artery. Thirteen patients were excluded because of incomplete records. There were no technical failures among the excluded patients. There were 41 male and 44 female patients with an average age of 56 years (range, 35-88 years) who met inclusion criteria. Risk factors included smoking (71%), hypertension (68%), diabetes mellitus (40%), and hyperlipidemia (26%).

In 85 patients, 112 distinct lesions were treated. Twelve lesions were sites of previous PTA. Indications for treatment were claudication (59%), rest pain (19%), tissue loss (17%), and prophylaxis for stenoses proximal or distal to bypass grafts (5%). Claudication occurred at one-half block in 60%, one block in 38%, and two blocks in 2%. The mean preprocedure resting ABI was 0.66 (range, 0.18-1.05).

Lesion characteristics are listed in Table I. Most lesions were located in the SFA. Most were stenoses less than 2 cm in length with good distal runoff.

Technical failure occurred in six (5.4%) of 112 lesions. Inability to cross the lesion with a guidewire was the cause of technical failure in one case and was considered both an immediate clinical and anatomic failure. In three cases, a residual stenosis > 30% was present after PTA, and in two cases, a flow-limiting dissection occurred. All five were successfully treated with stent deployment across the lesion and were therefore not considered immediate anatomic failures.

There were no procedural mortalities. Distal embolization to the anterior tibial artery occurred in one case and was resolved with catheter-directed thrombolysis. There were no cases of arterial rupture or acute arterial occlusion.

Cumulative clinical success was 69% at 1 year, 54% at 2 years, 49% at 3 years, and 40% at 4 years (Table II, Figure). Cumulative anatomic patency was 74% at 1 year, 62% at 2 years, 57% at 3 years, and 52% at 4 years (Table III, Figure). All patients underwent CDS so that anatomic patency could be assessed, and 53% also underwent angiography.

There were 45 cases of clinical failure after PTA.

Table III. Life table analysis of anatomic patency after PTA of the femoropopliteal arterial segment

Interval (mo)	*No. at risk at start of interval*	*No. of failures*	*No. withdrawn patent*	*Interval failure rate (%)*	*Interval patency rate (%)*	*Cumulative patency (%)*	*SE (%)*
0-1	112	3	10	2.8	97.2	97.2	1.5
1-6	99	17	13	18.4	81.6	79.3	3.6
6-12	69	4	12	6.3	93.6	74.3	4.5
12-24	53	7	20	16.3	83.7	62.2	5.2
24-36	26	2	8	9.1	90.9	56.5	7.3
36-48	16	1	7	8.0	92.0	52.0	9.0
48-60	8	0	4	0	100.0	52.0	12.7
> 60	4	3	1	85.7	14.3	7.4	3.6

Of the clinical failures, twenty-seven (60%) occurred in conjunction with anatomic failure at the PTA site, and eighteen (40%) occurred despite anatomic patency at the PTA site. The etiology for clinical failure is shown in Table IV. When clinical failure occurred in conjunction with anatomic failure at the PTA site, the most common cause was restenosis (44%), followed by occlusion at the PTA site (30%). When clinical failure occurred despite maintained anatomic patency at the PTA site, most failures were due to progression of disease at a site remote from the original PTA site but within the femoropopliteal segment (67%). The average time to clinical failure was 11.8 months (range, 0-61 months) when associated with anatomic failure and 15.2 months (range, 0-69 months) when associated with anatomic patency.

Table IV. Etiology of clinical failure after PTA of the femoropopliteal arterial segment (n = 45)

Clinical failure with anatomic failure (27)	
Restenosis	12 (44%)
Occlusion	8 (30%)
Restenosis and new femoropopliteal disease	6 (22%)
Technical failure	1 (4%)
Clinical failure despite anatomic patency (18)	
New femoropopliteal disease	12 (67%)
Iliac disease	3 (17%)
Tibial disease	2 (11%)
Bypass graft failure	1 (5%)

The management of clinical failures included observation, surgical bypass graft, and PTA (Table V). Supplemental PTA was performed in 50% of all clinical failures to treat recurrent stenoses or occlusions and to treat new femoropopliteal or iliac artery disease. Of the 12 restenoses, three were successfully redilated with PTA alone. Three required stent placement after PTA, two for a residual stenosis > 30% and one for a flow-limiting dissection. Of the eight reocclusions, three were successfully dilated with PTA alone, and two required selective stent placement, one for a residual stenosis > 30% and one for a flow-limiting dissection. Of the stents deployed, two were Palmaz stents (one in the SFA and one in the above-knee popliteal artery), and three were Wallstents (all in the SFA). Fifty percent of new femoropopliteal arterial segment disease was amenable to repeat PTA. All new iliac disease was treated percutaneously.

Surgical bypass graft was used to treat 37% of clinical failures. The nature of the surgical bypass graft was unchanged by the preceding PTA. Only one patient in our series of 85 patients had limb loss after PTA. This patient, treated for critical ischemia, required below-knee amputation after clinical failure following PTA and a failed surgical bypass graft.

DISCUSSION

Although PTA has become the treatment of choice for focal iliac occlusive disease, its role in infrainguinal disease remains unclear because of the variable success rates reported in the literature. The reported outcomes are variable because of differences in the criteria used to denote success and because of differences in the patient populations and the lesions treated.

Multiple factors have been shown to affect the results of femoropopliteal PTA. Patients with diabetes have worse outcomes than patients without diabetes.[3,4] Patients treated for critical ischemia have lower patency rates than patients treated for claudication.[4,6,10] Stenoses are associated with better patency than occlusions,[4-6,8] but the patency rates can be similar if initial technical failures are excluded.[4] Concentric lesions have been found to be more favorable than eccentric lesions,[4,7] and focal stenoses fare better than long-segment lesions.[2-4,7] In most studies, poor runoff correlates with worse outcomes.[5,7] A residual stenosis > 30% at the time of the procedure decreases the patency rate, whereas a focal, nonoccluding dissection does not appear to

Table V. Management of clinical failure after PTA of the femoropopliteal arterial segment

	PTA	*Bypass graft*	*Observation*
Clinical failure with anatomic failure (27)			
Restenosis (12)	6	5	1
Occlusion (8)	5	1	2
Restenosis and new femoropopliteal disease (6)	2	3	1
Technical failure (1)	0	1	0
Clinical failure despite anatomic patency (18)			
New femoropopliteal disease (12)	6	5	1
Iliac disease (3)	3	0	0
Tibial disease (2)	0	1	1
Bypass graft failure (1)	0	1	0
Total	22 (49%)	17 (38%)	6 (13%)

affect long-term prognosis.[4]

Primary stenting has not been shown to improve outcome compared with PTA alone.[17] However, selective stent placement for a residual stenosis > 30% or a flow-limiting dissection after PTA has shown acceptable patency rates of up to 65% at 4 years.[11,12]

Patency after PTA appears to be highest in patients with claudication who have focal stenoses and good runoff.[2,4-7] In this population, 5-year patency rates as high as 68% have been achieved.[2] Several authors have advocated angioplasty over surgical revascularization in such patients.[2,18] In one analysis of 26 published studies, angioplasty was preferred to surgery for patients with claudication. Even patients with critical ischemia and a stenosis (rather than occlusion) who underwent PTA fared better in terms of complication rates, outcomes, and cost compared with surgical bypass graft.[2] In our series of patients, which included patients with rest pain and ischemic tissue loss, anatomic patency rates of 74% at 1 year, 62% at 2 years, 57% at 3 years, and 52% at 4 years were achieved. These results are comparable to those reported in the literature.[3-8] Although we attempted to further classify our anatomic results according to lesion characteristics and indications for treatment, our data were too small for meaningful analysis. We tended to treat lesions that have been shown to respond favorably to PTA, on the basis of our previous experience with laser-assisted balloon angioplasty and the current literature.

Uniformity in reporting standards must be accomplished to better define the results of PTA. The Society for Vascular Surgery / International Society for Cardiovascular Surgery Subcommittee on Reporting Standards for Endovascular Procedures advocates that three criteria—symptomatic improvement, ABI improvement, and anatomic patency at the treated site—be present for the PTA procedure to be considered successful.[16] However, this recommendation is not ideal. Anatomic patency, with which the durability of the PTA procedure is measured, is not always associated with clinical and hemodynamic improvement.[9,19] Up to 17% of anatomically successful PTA sites will show no improvement in ABI, mostly because of distal multisegmental disease.[9] In another series of patients undergoing infrainguinal PTA for limb-threatening ischemia, less than 40% were observed to have hemodynamic improvement.[10] Resting ABIs are inaccurate predictors of restenosis at PTA sites.[9,14] In one group of patients, a 74% patency rate was found using a 0.15 improvement in the resting ABI as the sole criterion for success, but the actual anatomic patency was only 31% when these patients underwent angiography.[14] Exercise ABIs may be more accurate. However, not all patients can exercise, and the results are difficult to standardize. In addition, a hemodynamic deterioration cannot distinguish recurrent stenosis from new disease. Therefore, the requirement that hemodynamic success be achieved may underestimate the effectiveness of PTA.

We believe that clinical success is the most important outcome measure because the primary goal of therapy is to improve clinical symptoms. Anatomic patency at the PTA site is irrelevant if symptomatic improvement is not achieved. We analyzed our anatomic results using CDS and angiography to confirm that our ability to perform the procedure and our anatomic patency rates were comparable to other published reports, but our primary objective was to evaluate the clinical outcome of these procedures. We have achieved clinical success rates of 69% at 1 year, 54% at 2 years, 49% at 3 years, and 41% at 4 years. These are comparable to clinical success rates reported in the literature.[19] We have shown that although most clinical failures

occurred in conjunction with anatomic failure at the PTA site, a significant number of clinical failures occurred despite maintained anatomic patency at the PTA site. Therefore, anatomic patency does not guarantee clinical success.

In those patients with clinical failure in conjunction with anatomic failure at the PTA site, most failures occurred within the first year after treatment, which is consistent with other published reports.[4,7,20] Restenosis was the most common anatomic cause associated with clinical failure in this group (44%). Most recurrent lesions reported in the literature are due to restenosis rather than occlusion, even in lesions that were originally occlusions.[7] In addition, 22% of our patients with anatomic failure at the PTA site also had progression of disease remote from the PTA site but within the femoropopliteal segment. A femoropopliteal bypass graft was required in 50% of these patients because of the diffuse nature of the disease. However, we were able to perform supplemental PTA procedures in 48% of anatomic failures, all with immediate anatomic success. Because of the small number of secondary PTA procedures, we were not able to perform meaningful life table analyses of the clinical and anatomic success of these secondary procedures. However, several studies have demonstrated that secondary PTA procedures, even within a stent, are safe and associated with long-term success rates that are comparable to the primary procedure.[4,7,11-15] In our series, when surgical bypass graft was required, the nature of the bypass graft was unchanged by the preceding PTA. Previous reports have shown that repeat PTA does not alter the nature of subsequent arterial reconstruction.[4,7,13-15]

Despite anatomic patency, clinical failure occurred in 40% of our patients. Except for one case of a bypass graft failure distal to the PTA site, all of these clinical failures were due to progression of disease, most commonly within the femoropopliteal segment (67%). Nearly all new sites of disease occurred in areas of previously normal arteries or in arterial segments with previously minimal-mild disease (< 50% stenosis). New lesions tended to occur later than restenoses, usually after the first year after treatment, which is consistent with other reports.[20] Diffuse disease of the femoropopliteal arterial segment was treated with femoropopliteal artery bypass graft, whereas new, focal disease was amenable to PTA. New iliac lesions were the cause of clinical failure in 17% of patients, all of whom were treated with PTA. New tibial disease occurred in 11% of patients, one of whom underwent surgical bypass graft and one of whom was observed. Overall, 50% of the clinical failures with maintained patency at the PTA site were amenable to supplemental PTA of new femoropopliteal or iliac lesions.

The ability to manage clinical failures percutaneously, either with redilatation of the prior PTA site or with dilatation of new areas of disease stresses the importance of close clinical follow-up and CDS surveillance. Restenosis after PTA is most often due to myointimal hyperplasia and may progress to occlusion because of superimposed thrombus formation.[20] Surveillance using CDS can detect recurrent stenoses before progression to complete occlusion occurs. The technical failure rate is higher, and the anatomic patency rates are lower in cases of complete occlusion.[4,6-8] New lesions detected within the femoropopliteal segment or proximally within the iliac system may also be treated percutaneously and can be detected with serial CDS evaluations. According to our anatomic patency data, a CDS on the day after PTA is unnecessary because all anatomic failures within the first month were immediate failures at the time of the procedure. We recommend follow-up evaluation at 1 month, 6 months, and 12 months after the initial PTA and then at yearly intervals.

There are several limitations to our study. Our clinical assessment of walking distance in claudicants is based on patient interview, which may be inaccurate. We do not routinely use treadmill ABI testing unless the patient has symptoms of claudication despite a normal-resting ABI. To evaluate all patients solely to determine absolute walking distance is costly and time-consuming. However, this approach would have been more objective. In addition, we do not have information regarding subsequent procedures in patients who were lost to follow-up. We have made no effort to contact these patients because without direct clinical evaluation, we would only be able to assess their clinical status and be unable to assess their anatomic patency. Subsequently, we did not believe that any useful information for this particular manuscript could be obtained by attempting to contact this patient subgroup. Nevertheless, at a 4-year follow-up, we have meaningful life table data of clinical and anatomic results with an SE less than 10%. There was no significant difference in our results when we analyzed our data based on lesions versus patients.

As shown by the relatively small number of patients treated with PTA of the femoropopliteal arterial segment over a 7-year interval, we have maintained a fairly conservative approach.

Modification of risk factors and a walking program trial in claudicants are our first-line therapy. However, when this approach is not successful and patients have lifestyle-limiting claudication, rest pain, or tissue loss, an angiogram is performed. Focal disease that has been shown to respond favorably to PTA is generally treated percutaneously. Multilevel arterial segment disease, most often present in patients with critical ischemia, has been shown to respond poorly to treatment of only the proximal SFA or popliteal disease.[10] Occasionally, patients with tissue loss who had one-vessel runoff in continuity with the femoropopliteal lesion were treated in this study. Of these patients, 75% had single-vessel runoff, yet 66% of this group achieved clinical success or wound healing. The remaining 34% who failed clinically failed because of restenosis or occlusion at the PTA site, not because of progression of disease. The other patients with tissue loss who had two- or three-vessel runoff all achieved clinical success with femoropopliteal PTA. When we further evaluated the 18 patients who failed clinically despite anatomic patency at the PTA site, we found that 15 patients (83%) were treated for claudication, two (11%) for rest pain, and one (1.8%) for a stenosis proximal to a bypass graft. Fifty percent had three-vessel runoff, 28% had two-vessel runoff, and 39% had one-vessel runoff. We do not believe that multilevel disease, present at the time of PTA, was responsible for early clinical failure in these patients with maintained patency of the PTA site because the new disease occurred in areas of previously minimal-mild (< 50% stenosis) disease. In addition, we believe that after a walking program trial and risk factor modification, femoropopliteal PTA is an appropriate treatment option, other than observation alone, in patients with claudication and poor runoff. The performance of an infrageniculate bypass graft in a patient with claudication seems excessive.

In conclusion, we have shown that PTA is an acceptable therapeutic option for the treatment of short-segment disease of the SFA and popliteal artery. Although primary clinical success rates were inferior to surgical revascularization, supplemental PTA was possible in 50% of patients. Repeat percutaneous treatment may extend the interval of clinical success and may obviate the need for surgical bypass graft. Only with careful surveillance of the PTA site and adjoining arterial segments will the natural history of percutaneously treated SFA and popliteal artery be elucidated and recurrent or new lesions be detected. An understanding of the relationship between clinical and anatomic success will help determine the optimal treatment of femoropopliteal occlusive disease.

REFERENCES

1. Hunink MGM, Cullen KA, Donaldson MC. Hospital costs of revascularization procedures for femoropopliteal arterial disease. J Vasc Surg 1994;19:632-41.
2. Hunink MGM, Wong JB, Donaldson MC, Meyerovitz MF, deVries J, Harrington DP. Revascularization for femoropopliteal disease. JAMA 1995;274:165-71.
3. Hewes RC, White RI, Murray RR, Kaufman SL, Chang R, Kadir S, et al. Long-term results of superficial femoral artery angioplasty. AJR Am J Roentgenol 1986;146:1025-9.
4. Capek P, McLean GK, Berkowitz HD. Femoropopliteal angioplasty: factors influencing long-term success. Circulation 1991;83(Suppl I):I-70–80.
5. Johnston KW. Factors that influence the outcome of aortoiliac and femoropopliteal percutaneous transluminal angioplasty. Surg Clin North Am 1992;72:843-9.
6. Hunink MGM, Donaldson MC, Meyerovitz MF, Polak JF, Whittemore AD, Kandarpa K, et al. Risks and benefits of femoropopliteal percutaneous balloon angioplasty. J Vasc Surg 1993;17:183-94.
7. Matsi PJ, Manninen HI, Vanninen RL, Suhonen MT, Oksala I, Laakso M, et al. Femoropopliteal angioplasty in patients with claudication: primary and secondary patency in 140 limbs with 1-3 year follow-up. Radiology 1994;191:727-33.
8. Martin DR, Katz SG, Kohl RD, Qian D. Percutaneous transluminal angioplasty of infrainguinal vessels. Ann Vasc Surg 1999;13:184-7.
9. Samson RH, Sprayregen S, Veith FJ, Gupta SK, Ascer E, Scher LA. Inadequacy of the noninvasive hemodynamic evaluation of percutaneous transluminal angioplasty. Am J Surg 1984;147:212-5.
10. Parsons RE, Suggs WD, Lee JJ, Sanchez LA, Lyon RT, Veith FJ. Percutaneous transluminal angioplasty for the treatment of limb threatening ischemia: do the results justify an attempt before bypass grafting? J Vasc Surg 1998;28:1066-71.
11. Henry M, Amor M, Ethevenot G, Henry I, Amicabile C, Beron R, et al. Palmaz stent placement in iliac and femoropopliteal arteries: primary and secondary patency in 310 patients with 2-4 year follow-up. Radiology 1995;197:167-74.
12. Bergeron P, Pinot JJ, Poyen V, Benichou H, Khanoyan P, Rudondy P, et al. Long-term results with the Palmaz stent in the superficial femoral artery. J Endovasc Surg 1995;2:161-7.
13. White GH, Liew SC, Waugh RC, Stephen MS, Harris JP, Kidd J, et al. Early outcome and intermediate follow-up of vascular stents in the femoral and popliteal arteries without long-term anticoagulation. J Vasc Surg 1995;21:270-81.
14. Winter-Warnars HAO, van der Graff Y, Mali WPTM. Ankle-arm index, angiography, and duplex ultrasonography after recanalization of occlusions in femoropopliteal arteries: comparison of long-term results. Cardiovasc Intervent Radiol 1996;19:234-8.
15. Treiman GS, Ichikawa L, Treiman RL, Cohen JL, Cossman DV, Wagner WH, et al. Treatment of recurrent femoral or popliteal artery stenosis after percutaneous transluminal angioplasty. J Vasc Surg 1994;20:577-87.
16. Ahn SS, Rutherford RB, Becker GJ, Comerota AJ, Johnston KW, McClean GK, et al. Reporting standards for lower

extremity arterial endovascular procedures. J Vasc Surg 1993;17:1103-7.
17. Vroegindeweij D, Vos LD, Tielbeek AV, Buth J, Bosch HCM. Balloon angioplasty combined with primary stenting versus balloon angioplasty alone in femoropopliteal obstructions: a comparative randomized study. Cardiovasc Intervent Radiol 1997;20:420-5.
18. Wilson SE, Wolf GL, Cross AP. Percutaneous transluminal angioplasty versus operation for peripheral arteriosclerosis. J Vasc Surg 1989;9:1-9.
19. Matsi PJ, Manninen HI. Impact of different patency criteria on long-term results of femoropopliteal angioplasty: analysis of 106 consecutive patients with claudication. J Vasc Interv Radiol 1995;6:159-63.
20. Vroegindeweij D, Tielbeek AV, Buth J, Vos LD, van den Bosch HCM. Patterns of recurrent disease after recanalization of femoropopliteal artery occlusions. Cardiovasc Intervent Radiol 1997;20:257-62.

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DISCUSSION

Dr Cambria (Milwaukee, Wis). Could you break down for us the indication for interventions in your patients? And, in order to claim clinical success in the endovascular reporting standards, you have to have an improvement in ABI. Could you break down your ABI results as well?

Dr Karch. To answer your first question, about 60% of patients were treated for disabling claudication, 20% for rest pain, and the remainder for tissue loss. The main problem with the reporting standards is that for each lesion, success can be based on clinical improvement, hemodynamic or ABI improvement, or maintained anatomic patency. Dr Ahn's paper regarding the SVS/ISCVS Ad Hoc Subcommittee on Reporting Standards for Endovascular Procedures requires that all three of these criteria be fulfilled to denote success. However, there have been several studies that have shown that ABI results may be misleading, especially in the presence of more diffuse disease. Our average pre-PTA ABI was 0.66. We chose not to evaluate our results based on ABI since the goal of our study was to evaluate our clinical success and how that related to anatomic patency.

Dr Mansour (Maywood, Ill). That was a very nice paper, Dr Karch. I have two questions for you. The first one is whether there was any difference in the results following treatment of above-knee popliteal versus below-knee popliteal lesions. The second question relates to the number of lesions you dilated. You had 85 patients and 112 lesions. Do the patients that have more than one lesion dilated present with clinical failure more often than those that had single lesions?

Dr Karch. To answer your first question, the majority of our lesions were in the superficial femoral artery. Only 25% were in the popliteal artery, and therefore, the numbers were too small for meaningful life table analysis if broken down into the above-knee and below-knee location. Of the 45 clinical failures, 10 (22%) occurred following PTA of the popliteal artery. In addition, the clinical failure rate was the same in patients who underwent PTA of a single lesion and those who underwent multiple procedures.

Dr Schwartz (Chicago, Ill). I, too, enjoyed your presentation. Did you perform multivariate analysis to try to help us figure out which patients are good for this procedure? We would like to be able to predict which ones will have clinical success. Second, any report espousing the virtues of a procedure should probably include the complications of that procedure. Would you enlighten us as to your procedural complications?

Dr Karch. We did not perform a multivariate analysis. The objective of our paper was to determine the etiology and outcome of clinical failure following PTA. We did not analyze anatomic patency separately to determine the relationship of patency and lesion characteristics, runoff status, and patient demographics. However, there is extensive literature showing that stenoses have a better patency rate than occlusions, focal disease has a better outcome than long-segment disease, and more proximal lesions in the SFA do better than more distal SFA lesions and popliteal lesions. We did not look at these individual factors in our patient population.

In terms of our complication rate, distal embolization to the anterior tibial artery occurred in one patient and was successfully treated with catheter-directed urokinase infusion. There were no procedural mortalities, acute arterial occlusions, or arterial ruptures.

Dr Minion (Lexington, Ky). One quick question. You broke down your indications. I was wondering, did you find a difference in your clinical results for the groups with different indications? We have done a handful of these procedures. All of them have been for tissue loss, and I am still waiting for those ulcers to heal. I do not think we have seen a success for tissue loss with angioplasty.

Dr Karch. We performed the majority of procedures on patients with claudication and rest pain. We did not stratify our results based on the indication for the procedure since the data were small. I agree that patients with multilevel arterial segment disease, most often present in patients with critical ischemia, respond poorly to treatment of only the proximal SFA of popliteal disease. However, occasionally, we treated patients with tissue loss who had one-vessel runoff in continuity with the femoropopliteal lesion. Of these patients, 66% achieved wound healing. The remaining 34% who failed clinically failed because of restenosis or occlusion at the PTA site, not because of progression of disease. The other patients with tissue loss who had two- or three-vessel runoff all achieved clinical success with femoropopliteal PTA.

Dr Slesh (Willoughby, Ohio). With 60% of your patients being claudicants and an average preprocedural ABI of 0.6, it seems to me that your results are probably not as good as the natural history of the disease. And I do not know what disabling claudication is.

Dr Karch. Our first-line therapy in claudicants is modification of risk factors, smoking cessation, and a walking program. When this fails and the patient has lifestyle-limiting or disabling claudication and requests treatment, we proceed with angiography to determine whether PTA or surgical bypass are appropriate therapeutic options.

Dr Whitehouse (Ann Arbo, Mich). I have one other question for you. You described focal superficial femoral artery stenosis, and yet a focal stenosis may occur in a relatively undiseased vessel or a vessel with a fair amount of associated nonfocal disease. How aggressive are you willing to be? How disease-free does the rest of the SFA have to be for you to be willing to dilate the focal stenosis?

Dr. Karch. If a high-grade focal stenosis is present in association with mild nonfocal disease, I would treat the high-grade lesion with PTA. PTA is a low-risk procedure and does not "burn any bridges" since anatomic failure may be amenable to repeat PTA. We have also found that when surgical bypass is needed to treat clinical failure following PTA, the nature of the surgical bypass is unchanged by the preceding PTA. This has also been documented in the literature.